POSITIVE HEALTH CHECK EVALUATION TRIAL

PHC Consent

NCT Number: NCT03292913

Date: 05/22/2020

Attached Informed Consent Form is as follows: last received approval on 05/22/2020 – approval for the study overall ended on 12/17/2021

Positive Health Check
Participant Consent Form

THIS STUDY AND ITS PURPOSE

You are being asked to take part in a research study that is being conducted by RTI International. This study is funded by the Centers for Disease Control and Prevention (CDC) to test an online intervention that aims to help improve the health and wellbeing of people with HIV. You are one of 1,010 HIV-positive adults being asked to participate in this study.

DO I HAVE TO JOIN THIS STUDY?

Being in this study is completely voluntary. You can stop at any time. Your decision to take part in this study will not affect your access to any services or benefits.

WHAT WE'RE ASKING OF YOU

To take part in this 12 to 24-month study, you must agree to the following:

- The project coordinator will access your medical records four times throughout the study to verify your HIV status (when you enroll) and record your background information such as age and gender, CD4 count and viral load, appointment attendance, STD test results, and the medications you are taking to treat HIV. The project coordinator will access your medical records for the 24 months prior to participation in the research study and up to 24 months after you enroll in the study.
- You will be randomized into one of the two groups. Random assignment is like flipping a coin, so you will have a 50-50 chance of being in either group. If you are randomized to the Positive Health Check intervention group, you will be asked to complete the Positive Health Check intervention prior to your next three primary care appointments, including your appointment scheduled for today. With your permission, you may be approached to complete Positive Health Check during other services you receive at the clinic. Positive Health Check is an online tool that will give you information on how to improve your health and wellbeing based on answer choices that you select. You will be asked questions about your medication adherence, attendance at appointments, and sex behaviors. You can choose to skip certain questions but some questions do require an answer. The tool will generate a handout with questions for your providers and tips to practice at home that you select.
- If you are randomized to the control group, you will not complete the Positive Health Check intervention and you will continue to receive your normal care.

RISKS OF PARTICIPATION

There is a small risk that someone outside of the study may see your information. RTI is taking precautions to ensure your data remains safe and private. All data will be sent over secured servers and stored on servers that can only be accessed by the project team through password-protected accounts. When you enroll in the study, you will be assigned a random number to identify your data (described below in 'Respect for Your Privacy'). Identifying information will not be collected or transmitted to RTI or CDC in any way. The study database that links any of your personal information obtained through the study will be password protected, stored on a secure site at your clinic, and only be used by the project team at your clinic, not by RTI or CDC.

If you are randomized to the Positive Health Check intervention group, there is a small risk that completing the tool may make you feel uncomfortable or upset. You are able to skip over any question that you do not want to answer. You can stop using the tool at any time. The printed handout will not have your name or any identifying information on it. If you do not want to bring your handout outside of the clinic, you can give it back to the study coordinator and they will securely dispose of it.

BENEFITS OF PARTICIPATION

You might help other people with HIV by the knowledge gained from this study. If you are assigned to use the tool, it may help you to do a better job of taking care of your health.

COSTS OF PARTICIPATION

Taking part in the study will not cost you anything.

TOKEN OF APPRECIATION

You will be given a $50 gift card at the end of your study visit today. You will receive another $50 gift card at your last study visit 12-months from now.

RESPECT FOR YOUR PRIVACY

Any personal information (e.g., your name and telephone number) will be kept in locked file cabinets or on a password protected computer. When you enroll, we will assign you a special ID number that the project will use to identify your medical records. All of your records will be recorded under the ID number and not your name or anything else that can identify you.

Information collected from the Positive Health Check online tool will be identified only by your special ID number. RTI and CDC will not receive any identifying information and will not be able to link your answers back to you.

TERMINATING PARTICIPATION

You can stop taking part in this study by contacting the onsite project coordinator, [NAME], by phone (NUMBER) or email (EMAIL ADDRESS).

WHO TO CONTACT WITH QUESTIONS

The investigator in charge of this study at RTI International is Dr. Megan Lewis. You may call Dr. Lewis toll-free at 1-866-784-1958, extension 3-3613. You can call Dr. Lewis if you have any problems or questions related to this study.

If you have any questions about your rights as a research subject, you may ask RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number).

STATEMENT OF CONSENT FOR THE INTERVENTION STUDY

Signing the line below indicates that we have described the study procedures to you, asked you to take part, and given you the chance to ask questions. You do not give up any rights by signing this consent form. We can give you an unsigned copy of this form if you would like.

Do you have any questions?

By putting my signature on the line below, I am agreeing to take part in the Positive Health Check Evaluation study.

_____ _____

Date Signature of Individual